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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,211

06/02/2006

Ick-Dong Yoo

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JHK LAW

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EXAMINER

BLAKELY III, NELSON CLARENCE

ART UNIT

PAPER NUMBER

4131

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/596,211	<b>Applicant(s)</b> YOO ET AL.	
	<b>Examiner</b> NELSON C. BLAKELY III	<b>Art Unit</b> 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/02/2006</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Application Status***

Claims 1-6 of the instant application are pending. Claims 1-6 are under examination.

### ***Objections***

#### ***Specifications***

The disclosure is objected to because of the following informalities:

1. The use of the trademark SEPHADEX-LH20® has been noted on page 10 of the instant specification. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. On page 2, line 13, it appears that the word "dihydorxy-phenylalanine" is meant to be "dihydroxy-phenylalanine".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that *Penicillium* sp strain KCTC 26245 is required to practice the claimed invention. As such the biological material must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the *Penicillium* sp strain KCTC 26245.

The process disclosed in the specification does not appear to be repeatable, it is not clear that the invention will work with commonly available material and it is not apparent if the biological materials considered necessary to make and use the invention is both known and readily available to the public. A person skilled in the art could not make or use the invention defined in and commensurate with the claims without access to the specific biological material. It is noted that Applicant has deposited biological material but there no indication in the specification as to public availability. Therefore, a deposit at a recognized depository may be made to overcome this rejection.

If the deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicant, or by an attorney of record over his or her signature and registration number, or by someone in a position to corroborate the facts of the deposit, that the instant invention will be irrevocably and without restriction released to

the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit is a non-Budapest Treaty deposit, then in order to certify that the deposit meets the criteria set forth in 37 CFR §1.801-1.809 and MPEP §2402-2411.05, a statement, affidavit or declaration by Applicant, by an attorney of record over his or her signature and registration number, or by someone in a position to corroborate the facts of the deposit would satisfy the requirements herein by stating and providing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) provide evidence of the test of the viability of the biological material at the time of deposit (see 37 CFR §1.807);

(e) stating that the deposit will be replaced if it should ever become inviable; and

(f) the specification must state a date of deposit, deposit number, name and address of the depository, and a taxonomic description of the deposit.

It is noted that on page 9 of the instant specification, Applicant has satisfied most of the required components of (f); however, Applicant failed to provide the address of

the depository. Applicant is required to provide the address of the depository as specified by MPEP §1.805(b).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The inventive compound appears to be the compound of Formula 1 defined in the instant specification; however, the formula of claim 1 does not, in fact, correspond to the compound of the invention as disclosed. Accordingly, on page 7, line 1 of the instant application, there is a double bond in the R-group at position 1 of the cyclopentene, i.e.  $-\text{CH}=\text{CH}-\text{CH}_3$ , but the formula in claim 1 appears to be missing the double bond ( $=$ ), i.e.  $-\text{CH}_2-\text{CH}_2-\text{CH}_3$ . Examiner will interpret claim 1 as containing an apparent typographical error (i.e. the omission of the double bond) and, for the purposes of compact prosecution, will examine the claim as it reads upon the compound as claimed with the double bond in the R-group at position 1 of the cyclopentene.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase, "compound represented by the following formula 1 as an effective ingredient" concludes with a period, therefore, omitting Formula 1 from the metes and bounds of the claimed subject matter. For this

Art Unit: 1614

reason, the claim fails to specify what is, in fact, Formula 1, and is therefore indefinite.

For examination purposes, Examiner interprets the claim to include the formula recited *below* claim 1.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the trademark SEPHADEX-LH20® has been noted in instant claim 6. According to MPEP §2173.05(u):

If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

Therefore, claim 6 is properly rejected under the second paragraph of 35 U.S.C. 112.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamata *et al* (Agricultural and Biological Chemistry, Vol. 47, Issue 11, pp. 2637-2638, 1983; cited by Applicant).

Instant claim 1 recites a melanin biosynthesis inhibitor containing terrein compound represented by Formula 1, which is anticipated by Kamata *et al*, figure 1, compound III. It is duly noted that claims 2-4 are directed to the intended use of the product (the inhibitor as set forth in independent claim 1); however, Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Though Kamata *et al* does not specifically teach the terrein compound as being a melanin biosynthesis inhibitor or the intended uses as recited in claims 2-4, the instant compound, and that which is disclosed in the reference are physically, structurally, and materially synonymous, and therefore, must actually be capable of performing the intended use as claimed. While instant claim 1 also refers to terrein as “an effective ingredient”, Kamata *et al* discloses terrein as being a plant growth inhibitor, which anticipates the limitation of terrein as “an effective ingredient” if it is useful in the function of inhibiting plant growth.



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NELSON C. BLAKELY III whose telephone number is (571) 270-3290. The examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. C. B. III/  
Examiner, Art Unit 4131

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614

Application/Control Number: 10/596,211  
Art Unit: 1614

Page 9